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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,435	05/02/2006	Jeffrey D. Rothstein	JHU2090-1	2771

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,435	ROTHSTEIN ET AL.	
	Examiner	Art Unit	
	Stacey MacFarlane	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1, 14-17 and 19, drawn to an assay method for GTRAP3-18 binding proteins.

Group 2, claims 2-7, 9-17 and 19, drawn to an assay method using gene or protein expression, or activity.

Group 3, claims 8, 9-17 and 19, drawn to an assay method for compounds that disrupt complex formation between GTRAP3-18 and GTRAP3-18 binding proteins.

Group 4, claims 18, and 20-32, drawn to a method of treating.

Group 5, claims 33-36, drawn to a method of diagnosing a glycosylation-associated disorder.

Group 6, claims 37-41, drawn to a method of identifying subjects with a risk of glycosylation-associated disorder.

Group 7, claims 42-44, drawn to a method of monitoring effectiveness of treatment.

2. The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the corresponding special technical feature of all of the claims is a compound that binds to GTRAP3-18 or

modulates its activity. The following references demonstrate that GTRAP3-18 binding or modulating compounds have been described within the art. Butchbach et al. recite (in the Abstract) that GTRAP3-18 interacts with EAAT3 and that Methyl-β-cyclodextrin modulates GTRAP3-18 protein expression (*Methyl-beta-cyclodextrin but not retinoic acid reduces EAAT3-mediated glutamate uptake and increases GTRAP3-18 expression*. Journal of Neurochemistry 84(4):891-894. 2003). Ikemoto et al. demonstrate GTRAP3-18 mRNA is upregulated in response to morphine (Abstract of, *Identification of addicsin/GTRAP3-18 as a chronic morphine-augmented gene in amygdala*. Neuroreport 13(16):2079-2084. November 15, 2002). These references demonstrate that the corresponding special technical feature, a compound that binds to GTRAP3-18 or modulates its activity, does not make a significant contribution over the prior art, and for this reason the application lacks Unity of Invention.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

ALL Groups

A. (Claims 2, 3, 21, 22, 31, 33, 37, 44) GTAR3-18 nucleic acid expression, GTRAP3-18 polypeptide expression, **or** GTRAP3-18 activity.

Group 2

B: elect a **single** mode of detection (Claims 4-7): by levels of glutamate transport, by levels of GABA transport, by levels of dopamine transport, **or** by levels of amino acid transport. (If glutamate transporter is elected, further select from Group D.)

Group 2 and 3

C. elect a **single** GTRAP3-18 target molecule (Claims 11-13): GABA transporter, dopamine transporter, **or** amino acid transporter.

D. If glutamate transporter is elected then select one of the following (Claim 10) GLAST/EAAT1, GLT-1/EAAT2, EAAC1/EAAT3, EAAT4, **or** EAAT5.

Group 3 and 4

E. (Claims 15, 17, 24 and 26) inflammatory disorder, AIDS, cancer, neurologic or psychiatric disorder. If neurologic or psychiatric disorder is elected, further selecting from the following: (Claims 16 and 25) epilepsy, stroke, traumatic injury, chronic neurological disorders, Alzheimer's disease, amyotrophic lateral sclerosis, Parkinson's disease, Huntington's disease, spinocerebellar ataxia, neuromuscular disorders involving acute nerve or muscle injury, neuromuscular disorders involving chronic nerve or muscle injury, CNS inflammation, or schizophrenia.

Group 4

F. Mode of administration (Claims 27 and 28): formulation or gene therapy vector.

Group 6

G. agent (Claims 38 and 39): nucleic acid or antibody.

Group 7

H. (Claim 42) detecting level of GTRAP3-18 protein, mRNA, genomic DNA, or level of glycosylation of a specific protein.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

The claims are drawn to binding or modulation of GTRAP3-18 expression or activity and the diseases/disorders to which GTRAP3-18 may play a role.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: they comprise materially and functionally distinct species that lack a unifying feature by which they are tied to GTRAP3-18 modulation.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on Monday-Thursday 7:00AM-4:30 PM & ALT. Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZACHARIAH LUCAS
PATENT EXAMINER